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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.            |
|--|-------------|----------------------|---------------------------------|-----------------------------|
| 10/560,924   | 12/13/2006  | Jon Bondebjerg       | 4614-0185PUS1                   | 4359                        |
| 2252   | 7590        | 06/12/2009           |                                 |                             |
| BIRCH STEWART KOLASCH & BIRCH<br>PO BOX 747<br>FALLS CHURCH, VA 22040-0747 |             |                      | EXAMINER<br>YOUNG, SHAWQUIA     |                             |
|  |             |                      | ART UNIT<br>1626                | PAPER NUMBER                |
|  |             |                      |                                 |                             |
|  |             |                      | NOTIFICATION DATE<br>06/12/2009 | DELIVERY MODE<br>ELECTRONIC |
|  |             |                      |                                 |                             |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

|                              |                                      |  |
|------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/560,924 | <b>Applicant(s)</b><br>BONDEBJERG ET AL. |
|                              | <b>Examiner</b><br>SHAWQUIA YOUNG    | <b>Art Unit</b><br>1626                  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 04 February 2009.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 1-4, 12, 13, 17-35 and 37 is/are pending in the application.  
 4a) Of the above claim(s) 27-35 is/are withdrawn from consideration.  
 5) Claim(s) 24-26 is/are allowed.  
 6) Claim(s) 1-4, 12, 13, 17-23 and 37 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-4, 12, 13, 17-35 and 37 are currently pending in the instant application. Applicants have cancelled claims 5-11, 14-16 and 36 in an amendment filed on February 4, 2009. Claims 1-4, 12, 13, 17-23 and 37 are rejected, claims 24-26 are allowed and claims 27-35 are withdrawn from consideration.

#### **I. *Response to Arguments/Remarks***

Applicants' amendment, filed on February 4, 2009, has overcome the rejection of claims 20-23 under 35 USC 112, first paragraph as failing to comply with the enablement requirement; the rejection of claims 1-3, 9-11, 13 and 15 under 35 USC 102(b) as being anticipated by Altmann, et al. and the objection of claims 1-26 as containing non-elected subject matter. The above rejection and objection have been withdrawn.

Applicants have amended claim 1 to include the proviso language "with the proviso that the compound of formula (I) is not H-Leu-Leu(CN)". However, the proviso language is not supported by the specification. Applicants state that support for the proviso language can be found at page 2, lines 30-31 of the instant specification.

Applicants further state in the arguments that the instant specification incorporates by reference the WO 99/24460 publication which specifically teaches this compound as an intermediate on page 50, paragraph and that the publication is incorporated by reference on page 38, lines 4-6 in the instant specification. However, the Examiner wants to point out that Applicants' incorporation by reference for this specific

intermediate compound is considered ineffective. The attempt to incorporate subject matter into this application by reference to WO 99/244460 is ineffective because Applicants have only provided a general statement on page 38 which reads "The various references to journals, patents and other publications which are cited herein comprise the state of the art and are incorporated herein by reference as though fully set forth". According to *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973), "the incorporation by reference in an application of matter elsewhere written down, for economy, amplification, or clarity of exposition, by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found". Also according to *Advanced Display Systems, Inc.*, 212 F. 3d 1272, 54 USPQ 2d 1673 (Fed. Cir. 2000), "to incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents."

Applicants' specification contains an incorporation by reference statement broadly referring to several patents, publications, journal references, etc. with no specific indication of the relevance of each to the claimed invention and as a result adding a specific intermediate compound that is disclosed in the WO 99/244460 publication is considered new matter since Applicants have failed to clearly identify what subject matter is being incorporated by reference. Therefore, the Examiner is going to proceed as if no incorporation by reference statement has been made (See MPEP 608.01(p)) and reject the claims under 112, first paragraph as containing new matter.

**II. Rejection(s)**

***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-4, 12, 13, 17-23 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have amended the claim 1 to include the proviso language "with the proviso that the compound of formula (I) is not H-Leu-Leu(CN)" but this proviso language is not disclosed in the original specification and is considered new matter because the amendment introduces subject matter that is not supported by the original disclosure. The original specification does not disclose the compound H-Leu-Leu(CN) so therefore Applicants can not add proviso language excluding this specific compound because there is not support. Applicants are suggested to delete the proviso language in claim 1 to overcome the new matter rejection.

**III. Conclusion**

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/  
Examiner, Art Unit 1626

/Rebecca L Anderson/  
Primary Examiner, Art Unit 1626